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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,798	02/12/2002	Hisao Hiramatsu	10873.872USWO	6236
23552	7590	06/10/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HYUN, PAUL SANG HWA	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,798	HIRAMATSU ET AL.	
	Examiner Paul S. Hyun	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/12/02.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8 and 10-13 is/are rejected.
 7) Claim(s) 9 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 2/12/02 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>May 10, 2002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

Drawings

The drawings are objected to because reference 10 of FIG 4, the word "ber" is misspelled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not include a transition phrase (i.e. "steps comprising") that is necessary to clearly define the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. (U.S. Patent Application US 2001/0051377 A1).

In reference to claim 1, Hammer et al. discloses a cartridge-based analytical instrument that conducts measurements. The cartridges used with the instrument are pre-loaded with samples and reagents (see [0008] Summary of the Invention) wherein the sample and the reagent are held separately within a cartridge, the sample held in system 76 and the reagent held in reagent pouch 98.

Even though the reference is silent towards a distinction between a “special-purpose cartridge container” and a “general-purpose cartridge container” by whether or not an information carrier is attached to a cartridge, it appears that the instrument is capable of distinguishing between two such types of cartridge containers by utilizing information carriers in the form of bar codes. The reference discloses that the instrument can be configured to conduct a single type of analytical test (used for “special-purpose cartridges”) or various types of analytical tests (used for “general-purpose cartridges”) {see [0008] Summary of the Invention}, the nature of the protocol determined by the information that each cartridge carries on a bar code 106 (see [0061] Detailed Description). However, Hammer et al. do not teach using no label on “general-purpose” cartridges and labels on “special-purpose” cartridges.

Nonetheless, it is well known in the art of labeling or tagging to simplify identification as much as possible for ease of recognition. It would have been obvious to provide the absence of a bar code on general-purpose cartridges in order to provide a

visual indicator of the cartridge distinction as well as faster, simpler computer identification.

In reference to a carrier identification means, the reference discloses a bar code reader 200 that reads what information is stored in the bar code.

The reference also discloses a disk inlet 22 that can accept a floppy disk that communicates with a central processing unit (CPU) (not pictured) located in the upper housing cover 14. The floppy disk is used to transport data and information into and out of the central processing unit (see [0050] Detailed Description of the Invention). Moreover, according to The Free On-Line Dictionary of Computing, CPU is "part of a computer that controls all other parts. The CPU also comprises memory, including RAM, cache, registers and ROM." Based on this definition, it appears that the invention disclosed by Hammer et al. is capable of storing information regarding measurement conditions.

In reference to the operation control means, the reference discloses that the CPU directs the tracking and control system 30 that coordinates the proper measurement operation after receiving the information from the bar code reader. Based on this information, the tracking and control device controls the rotary drive mechanism for the cartridge rotor plate and the actuators which operate against the flexible septums and flexible reagent pouches (see [0061] Detailed Description). The tracking and control system also includes a user input interface for receiving data from the operator of the instrument regarding test protocols (see [0012] Summary of the invention). This feature

would be useful for conducting tests for "general-purpose cartridges" that require manual operation of the instrument.

In reference to claim 2, the Hammer et al. reference further discloses an information carrier in the form of a bar code 106, which is optically readable. The invention further comprises a bar code reader 200, which is disposed in means for mixing the sample with the reagent(s).

In reference to claim 3, the Hammer et al. reference further discloses the invention's ability to accept floppy disks that contain pertinent information (see [0050] Detailed Description of the Invention). According to The American Heritage Dictionary of the English Language, Fourth Edition, a floppy disk is "a flexible plastic disk coated with magnetic material and covered by a protective jacket, used primarily by computers to store data magnetically." The CPU of the instrument reads the information stored in the floppy disk and stores the information in its information storage means.

In reference to claim 4, the Hammer et al. reference discloses that the CPU is capable of storing information regarding measurement conditions. According to The Free On-Line Dictionary of Computing, CPU is "part of a computer that controls all other parts. The CPU also comprises memory, including RAM, cache, registers and ROM." Based on this definition, it appears that the invention disclosed by Hammer et al. is capable of storing information regarding measurement conditions for "special-purpose

cartridges" separately from the information regarding measurement conditions for "general-purpose cartridges."

The CPU is also capable of analyzing the measurement conditions stored in a recording medium, such as a floppy disk, and store the information accordingly, depending on whether the information corresponds to a "special-purpose cartridge" or a "general-purpose cartridge."

In reference to claim 5, the Hammer et al. reference discloses the use of bar codes 106 to identify cartridges. The American Heritage Dictionary of the English Language, Fourth Edition defines bar codes as "a series of vertical bars of varying widths, in which each of the digits zero through nine are represented by a different pattern of bars that can be read by a laser scanner." Therefore, it appears that by utilizing bar codes, a specific, non-overlapping identification number is given to each cartridge disclosed in the Hammer et al. reference.

In reference to claim 6, Hammer et al. reference further discloses that all the reagents and samples are pre-loaded into the cartridges (see [0008] Summary of the Invention).

In reference to claim 8, Hammer et al. discloses a measuring method using a cartridge in which a sample and a reagent are injected separately (see [0008] Summary of the Invention). Even though the reference is silent towards a distinction between a

"special-purpose cartridge container" and "general-purpose cartridge container" by whether or not an information carrier is attached to a cartridge, it appears that the instrument is capable of distinguishing between the two types of cartridge containers. The reference discloses that the instrument can be configured to conduct a single type of analytical test (used for "special-purpose cartridges") or various types of analytical tests (used for "general-purpose cartridges") {see [0008] Summary of the Invention}, the nature of the protocol determined by the information the cartridge carries in the form of a bar code 106 (see [0061] Detailed Description). However, Hammer et al. do not teach using no label on "general-purpose" cartridges and labels on "special-purpose" cartridges.

Nonetheless, it is well known in the art of labeling or tagging to simplify identification as much as possible for ease of recognition. It would have been obvious to provide the absence of a bar code on general-purpose cartridges in order to provide a visual indicator of the cartridge distinction as well as faster, simpler computer identification.

Furthermore, the invention includes a user input interface for receiving data from the operator of the instrument regarding test protocols (see [0012] Summary of the Invention). This feature would be useful for conducting tests for "general-purpose cartridges" that require manual operation of the instrument.

In reference to claim 10, Hammer et al. discloses the use of a floppy disk that can be inserted into the instrument to provide software updates as well as transport

other data and information into and out of the central processing unit (see [0050] Detailed Description of the Invention). Since the floppy disk can be used to provide software updates, it appears that that the floppy disk can also be used to execute the control program run by the instrument wherein the control program comprises; distinguishing between a "special-purpose cartridge" and a "general-purpose cartridge" based on the output from the bar code reader, and executing the measurements wherein if the cartridge is a "special-purpose cartridge," the program conducts the measurement following the conditions read out from the bar code and if the cartridge is a "general-purpose cartridge," the program outputs an instruction on the user input interface for receiving data from the operator of the instrument regarding the test protocols.

In reference to claim 11, Hammer et al. discloses the use of a floppy disk that can be inserted into the instrument to provide software updates as well as transport other data and information into and out of the central processing unit (see [0050] Detailed Description of the Invention). Since the floppy disk can be used to provide software updates, it appears that that the floppy disk can also be used to execute the control program run by the instrument wherein the control program comprises deciding whether the measurement conditions relate to a "special-purpose cartridge" or a "general-purpose cartridge" based on the information stored in the bar code, and storing the information separately in the memory of the CPU.

In reference to claim 12, the Hammer et al. reference discloses the program medium and it further discloses the use of bar codes 106 to identify cartridges. The American Heritage Dictionary of the English Language, Fourth Edition defines bar codes as "a series of vertical bars of varying widths, in which each of the digits zero through nine are represented by a different pattern of bars that can be read by a laser scanner." Therefore, it appears that by utilizing bar codes, specific, non-overlapping identification number is given to each cartridge disclosed in the Hammer et al. reference.

In reference to claim 13, the Hammer et al. reference discloses the program recording medium and it further discloses the use of a floppy disk, which is "a flexible plastic disk coated with magnetic material and covered by a protective jacket, used primarily by computers to store data magnetically," according to the American Heritage Dictionary of the English Language, Fourth Edition.

The CPU of the instrument is capable of reading the magnetic information stored in the floppy disk and execute the program according to the information.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. in view of Petersen et al. (U.S. Patent Application US 2001/0012612 A1). Hammer et al. discloses the invention as mentioned, but it is silent towards a waste vessel disposed in the cartridge container to store waste liquid.

Petersen et al. discloses a method for analyzing fluid samples that utilizes a multi-vessel cartridge wherein chamber 68 is used to store waste. It would have been obvious to one of ordinary skill in the art to incorporate a waste vessel as taught by Petersen et al. in the cartridge disclosed by Hammer et al. so that waste material from the analysis can be separated for easy disposal.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Devlin et al. (U.S. Patent Application US 2002/0064884 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PSH 5/13/05


Jill Warden
Supervisory Patent Examiner
Technology Center 1700